DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-280/S-031

Pharmacia & Upjohn Company
Attention: Cynthia Blanchard
Regulatory Manager
7000 Portage Road
Kalamazoo, MI 49001

Dear Ms. Blanchard:

Please refer to your supplemental new drug application dated June 30, 2002, withdrawn on October 17, 2000, and resubmitted on January 25, 2001, received January 26, 2001, under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Genotropin (somatropin [rDNA origin] for injection).

We acknowledge receipt of your submissions dated March 21, April 24, June 19 and 26, and July 2, 3, 11, 12, 13, 23, 2001.

This supplemental new drug application provides for the use of Genotropin (somatropin [rDNA origin] for injection) for long-term treatment of growth failure in children born small for gestational age who fail to manifest catch-up growth by two years of age.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

You are not required to complete a pediatric assessment for this application because it is not covered by the Pediatric Rule (21 CFR 314.55(a)).

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted July 12, 2001), which is also enclosed.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-280/S-031." Approval of this submission by FDA is not required before the labeling is used.

In reference to your proposed postmarketing commitments (submission dated July 23, 2001), we are not requiring these as part of a Phase 4 agreement. However, we believe the study information will be valuable. We encourage you to continue your work in these areas.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Crystal King, P.D., M.G.A., Regulatory Project Manager, at (301) 827-6423.

Sincerely yours,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure